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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE BIOGEN '755 PATENT LITIGATION

: Civil Action No.: 10-cv-02734 (CCC) (JAD)

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DEFENDANTS' SUPPLEMENTAL CLAIM CONSTRUCTION BRIEF

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Biogen's admissions over the course of the briefing and the *Markman* hearing have significantly narrowed the scope of the parties' dispute regarding claim construction. Although it previously contested the point, Biogen now admits that the "produced" and "transformed" limitations of its claims are "affirmative limitations" and that "there is no dispute that . . . the product that you give the patient . . . has to include a polypeptide *produced* by a non human host that was *transformed* with a micro DNA." Transcript of *Markman* Hrg., ECF No. 194 ("Tr.") at 65:2-14. (emphasis added). The remaining dispute is about whether, as Biogen claims, those "affirmative limitations" should somehow be exempt from the rules that govern all other process limitations as a matter of settled law; *i.e.*, that they must be carried out during the term of the patent and in the United States.

Biogen fails to point to a single case that supports this assertion, but nonetheless argues that the usual rules governing process limitations do not apply because its claims incorporate a process "nested like Russian dolls" inside another process. Tr. at 83:4-6. That is, Biogen nested a process for producing a polypeptide within a process of administering the polypeptide, and now claims that the law treats those processes differently. Biogen cites no authority whatsoever for this proposition, and indeed, it has repeatedly asserted that there is no case on point. *E.g.*, Tr. at 61:9-14, 63:12-16, 79:8-15, 100:9-10. Biogen is wrong; the Federal Circuit addressed this precise issue in *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1357-60 (Fed. Cir. 2007). In *Monsanto*, the Federal Circuit unequivocally stated that a claim to a process of using a product obtained by another process—the exact structure of Biogen's claims—requires that all of the process limitations must be performed after the patent issues, including the processes that are "nested" within the claims.

Biogen's arguments are as meritless as they are unsupported. Its principal argument invites the Court to ignore the Federal Circuit's holding in *Monsanto* on the basis that it would yield an "absurd" result. Tr. 61:15-18; Biogen's Reply Br., ECF No. 153 at 7. Biogen cited no authority directing the Court to follow this results-oriented approach to claim construction, and the Federal Circuit has repeatedly rejected it.¹ But even if it were permitted, there is nothing absurd about insisting that the "produced" and "transformed" limitations are subject to the same rules as every other process limitation. Biogen prosecuted the '755 patent, Biogen relied on those limitations to procure issuance of the '755 patent, and Biogen now agrees they recite a process for producing the polypeptide of the claims.

Requiring that these process steps be treated like all other process limitations, and thus, e.g., carried out during the term of the patent, is especially appropriate here given that Biogen used the "produced" and "transformed" limitations to distinguish its claims from the prior art. '755 patent, ECF No. 118-1 at 7:8-14. Likewise, Biogen is wrong to argue that the restriction requirement—an administrative action during prosecution—requires this Court to treat the claims as though they were methods of treatment that did not recite the "produced" and "transformed" limitations. Tr. at 71:1-73:18. Biogen's argument is unsupported and rests on multiple misstatements of the law. The Court should follow the Federal Circuit's established law relating to process limitations and decline Biogen's invitation to fashion a new rule of law that a claim limitation may define a process, yet need not be carried out during the term of the patent or in the United States.

¹ The Federal Circuit unequivocally has instructed that even "a nonsensical result does not require the court to redraft the claims" of a patent. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357 (Fed. Cir. 1999); *Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1373-74 (Fed. Cir. 2004) (adopting interpretation of claim that would yield absurd result that patentee could not have intended).

I. THE “PRODUCED” AND “TRANSFORMED” LIMITATIONS MUST BE PERFORMED DURING THE TERM OF THE PATENT

A. There Is No Dispute That “Produced” and “Transformed” Are Process Limitations.

The parties do not dispute that every claim of Biogen’s patent requires, *inter alia*, “administering to a patient” a composition containing a “recombinant polypeptide produced by a non-human host transformed by a recombinant DNA molecule,” nor do they disagree about the meaning of the terms, including “administering,” “produced,” and “transformed.” ECF No. 179 at 1-2. The principal remaining dispute involves whether the claims require that the “produc[ing]” and “transform[ing]” occur during the term of the patent.² Two key concessions by Biogen at the hearing have simplified the issues and, in view of Federal Circuit law, resolve the dispute.

First, Biogen now concedes that the “polypeptide” limitation uses what the law calls “product by process” language. Tr. at 59:11-17. A product-by-process claim is a way of describing a product by how it is made instead of what it is. *E.g., Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1291 (Fed. Cir. 2009) (en banc in relevant part). While Biogen’s claims as a whole are to methods rather than “products,” the polypeptide limitation at issue here is described by how it is made—it is “produced” by a “transformed” host—and not based on its structure.

Gemtron Corp. v. Saint-Gobain Corp., 572 F.3d 1371, 1379 (Fed. Cir. 2009); *In re Hughes*, 496

² Defendants also contend that the “produc[ing]” and “transform[ing]” must occur within the United States, following the ordinary rule that infringement requires each process step to be performed in this country. *See NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1318 (Fed. Cir. 2005) (“[A] process cannot be used ‘within’ the United States as required by [35 U.S.C.] section 271(a) unless each of the steps is performed within this country.”). This Supplemental Brief primarily focuses, however, on the question of *when* the limitations must be performed rather than *where*, because the question of *when* may decide the entire case—the evidence will show that *none* of the Defendants has ever “transformed” within the meaning of the claims during the term of the patent. The issue of territoriality will be further addressed, if necessary, at a later time.

F.2d 1214, 1218-19 (C.C.P.A. 1974); *see also* Defs.’ Reply Br., ECF No. 152 at 8-12; Tr. at 123:1-124:22; Jackson Dep., ECF No. 152-2 at 174:16-178:14, 181:6-17. In other words, “polypeptide” is a product-by-process limitation, and “produced” and “transformed” are process steps to prepare the polypeptide.

Second, Biogen has conceded that “produced” and “transformed” are “affirmative limitations” that the claim requires must actually be performed. Tr. at 64:21-65:14. Biogen’s counsel stated at oral argument that “the recombinant polypeptide must have been produced using the transformed host.” Tr. at 83:22-84:2; *see also* Biogen’s Resp. Br., ECF No. 145 at 12 (“These are undisputedly claim elements that must be met to prove infringement[.]”). Biogen’s concession simply followed the Federal Circuit’s *en banc* decision in *Abbott* that “process terms that define the product in a product-by-process claim serve as enforceable limitations.” *Abbott*, 566 F.3d at 1291-93.³

The legal consequence of these concessions, regardless of what label is affixed to the claim as a whole, is that the “produced” and “transformed” limitations are process steps. Those steps were necessary to procure issuance of the claims and are enforceable limitations that require the specified acts to be performed; indeed, that is what a “step” is. *Abbott*, 566 F.3d at 1291-92 (referring to the enforceable process limitations of a product-by-process claim as “process steps” even though the claims did not use the word “step”); *Monsanto*, 503 F.3d at 1355, 1357 (referring to “the last step of the process of claim 4” even though the claim did not use the word “step”).

³ Biogen relies on the distinction that its claim is a method claim rather than a product claim to try to distinguish product-by-process case law such as *Abbott*. See Tr. at 59:8-19. Biogen’s arguments are untenable—there is, if anything, less reason for a court to decline to apply the usual rules for process claims here, where the claim is a process claim. See *Monsanto*, 503 F.3d at 1358, 1360; *Ex parte Ellul*, 2012 WL 4339538 (B.P.A.I. Sep. 20, 2012); *infra* Section I.B; *see also* 35 U.S.C. § 100(b) (defining “process” as synonymous with “method”).

B. Monsanto Requires the “Produced” and “Transformed” Steps To Have Been Performed During the Term of the Patent.

Thus, the only dispute between the parties is about the *legal effect* of the “produced” and “transformed” process limitations. Under controlling Federal Circuit law, such process limitations must be performed, like any other process limitation, during the term of the patent. *See* 35 U.S.C. § 271(a); *Monsanto*, 503 F.3d at 1359-60. Biogen argues that the “architecture” of the claim means that only the first process limitation, the “administering” step, is subject to this rule because the other process limitations are “nested” within the administering step. Biogen cites no authority whatsoever for this novel proposition. Indeed, although Biogen assured the Court that this is “absolutely” a typical structure for writing claims (it is not), Biogen was forced to concede that it has no authority to support its construction of such allegedly “typical” claims. Tr. at 61:9-14, 63:12-16, 79:8-15, 100:9-10, 101:2-8.

In fact, there is a case directly on point, and it controls the outcome here: *Monsanto v. Syngenta*.⁴ One of the claims at issue in *Monsanto*, claim 4 of the ’880 patent, is indistinguishable in structure from Biogen’s. The invention in *Monsanto* involved inserting DNA into corn to create so-called “transgenic” corn plants with resistance to a particular herbicide. 503 F.3d at 1354. *Monsanto* claim 4 covered the process of “obtaining progeny” from such a transgenic corn plant. *Id.* at 1355. That transgenic corn plant was defined by the process used to make it; it had to be “obtained by the process of claim 1.” *Id.* *Monsanto* claim 1

⁴ Since the *Markman* hearing, the Patent’s Office’s Board of Patent Appeals and Interferences has also addressed the interpretation of claims that, like Biogen’s, recite a process for using a product made by a process. Tr. 63:22-65:14, 82:20-84:2. It rejected the suggestion that the nested claim format changed any rules and held that the “product-by-process principle applies even in the context of a process claim that recites a step of using a product that is defined by the method by which it is produced.” *Ellul*, 2012 WL 4339538 (citing *In re Hirao*, 535 F.2d 67, 69 (C.C.P.A. 1976)).

in turn defined the method of making the transgenic corn plant by inserting the DNA that conferred herbicide resistance into corn. *Id.* at 1357.

Thus, like Biogen's claims, *Monsanto* claim 4 was directed to a process ("obtaining progeny"), and that process required the use of a product (a "transgenic plant") made in accordance with specified process limitations ("the process of claim 1"). In both *Monsanto* claim 4 and Biogen's claims here, there is a process step—"obtaining progeny" in *Monsanto* and "administering" in this case—that makes use of a product—the "transgenic plant" in *Monsanto* and the "polypeptide" here. And just as the *Monsanto* claim contains process limitations that specify how the plant is made, Biogen's claims recite process limitations ("produced" and "transformed") to define how the polypeptide is made. Both this case and *Monsanto* therefore involve claims to a process of using a product made by a specified process. The "architecture" of these claims is indistinguishable, and the rule of *Monsanto* is therefore directly applicable.⁵

Much like "transformed" host cells, a transgenic plant can pass its DNA on to its progeny, and in *Monsanto*, the process of making the first transgenic corn plant occurred before the patent issued. The accused infringer in *Monsanto* thus made the same argument that Defendants make here—that process limitations must, as a matter of law, be performed during the term of the patent. In response, the patentee made the same arguments that Biogen makes here. It argued that the defendant could still meet claim 4 "by completing the last step of 'obtaining progeny' during the patent term (albeit with the first three steps occurring before the patent issued)." *Id.* at 1359. In other words, the patentee argued that the process claim could be

⁵ Claim 4 of *Monsanto* does not explicitly recite the process steps used to obtain the transgenic plant, but instead requires it to be obtained "by the process of claim 1." That claim format, known as a dependent claim, simply incorporates claim 1 into claim 4 by reference; "claims in dependent form include all the limitations of the claim incorporated by reference into the dependent claim." *Monsanto*, 503 F.3d at 1359; see 35 U.S.C. § 112(d) (formerly § 112 ¶ 4). It is therefore not a relevant distinction between the claim in *Monsanto* and the claims in this case.

infringed even if the nested process steps occurred only before the patent issued. The Federal Circuit rejected this argument. It held, under a “basic rule,” that because the steps of claim 1 were carried out “before patent issuance,” claim 4 was not infringed. 503 F.3d at 1359-60. That decision is binding here, and it requires, at a minimum, that the “produced” and “transformed” limitations be carried out during the term of the ’755 patent.⁶

Biogen has also argued that its claims are to “a method of treatment consisting of a single step, just the one step, administering a recombinant polypeptide.” Tr. at 80:11-13. *Monsanto* forecloses this argument too. Monsanto argued that claim 4 was “by itself a single-step process (process of obtaining progeny),” and that claim 4 merely referenced the starting material for carrying out that single-step process. 503 F.3d at 1357-58. The Federal Circuit rejected this argument, and held that the purported single step of “obtaining progeny” was in reality one of four steps, the other steps being the process of producing the original transgenic corn plant. *Id.* at 1358. Thus, it held, “[e]ven if claim 4 is a product by process claim, [the accused infringer] would still have to perform the steps of the process of claim 1 to infringe the product by process claim.” *Id.* Moreover, contrary to Biogen’s arguments that this case hinges on the term “step” or the verb tenses of the claim limitations, the Federal Circuit concluded that *Monsanto* claim 4 had more than one process step even though claim 4 did not use the word “step” and despite claim 1’s use of the past-tense term “obtained.” 503 F.3d at 1355.

Biogen also relies on the fact that during prosecution of the *Monsanto* patent, the original draft of claim 4 had four explicit steps (without any product-by-process language) and was then amended into its final form with a statement by the examiner that the amendment did not

⁶ Defendants contend, and Biogen does not appear to dispute, that they last “transformed” a host cell in connection with manufacturing their products long before the ’755 patent issued. Additionally, Serono and Pfizer contend, and Biogen does not appear to dispute, that any transformation only ever occurred outside the United States.

“affect[] the scope of the invention.” 503 F.3d at 1358. But there is no suggestion in *Monsanto* that the Court’s holding would have been different but for this prosecution history. To the contrary, the prosecution history only provided “additional insight” that “underscored” that the plain language of the claim, which shared the structure of the claim here, set forth a process for using a product-by-process, and thus incorporated additional process steps.

C. Biogen’s Representations to the PTO During Prosecution Foreclose Its Attempted Re-Interpretation of the Claims

The prosecution history here, as in *Monsanto*, underscores that the claims require more than a single “administering” step. During prosecution, Biogen described the “produced” and “transformed” limitations as “positive process steps” and agreed at the time—as it did at the *Markman* hearing—with the Examiner’s characterization that “the claims *require the use of the DNA to produce the polypeptides.*” ECF No. 118-8 at 3-4; ECF No. 118-11 at 2-3; *see, e.g.*, Defs.’ Resp. Br., ECF No. 148 at 9-10. In the face of this evidence, Biogen attempted (without any supporting evidence) to characterize its admissions that the claim has multiple “positive process steps” as a “mistake.” Tr. at 95:12-96:5. Indeed, Biogen’s counsel suggested this was merely a one-time slip-up in thirty years of prosecution, as if Biogen were otherwise consistent in its position that “produced” and “transformed” were not “positive process steps.” To the contrary, Biogen does not point to a single instance during those thirty years when it ever described these limitations as anything *other than* “positive process steps,” and indeed, Biogen described them precisely this way on multiple occasions. ECF No. 118-8 at 3-4; ECF No. 118-11 at 2-3. Only now, with all that is at stake in this litigation, and having procured its patent from the PTO by telling the Examiner otherwise, is Biogen for the first time in those thirty years asserting that “produced” and “transformed” are *not* “positive process steps.”

Indeed, when the Examiner addressed what is now claim 1 of the '755 patent and co-pending claim 31 of Biogen's '723 application (each of which contained the same "produced" and "transformed" language and differed only in the intended medical uses of the polypeptide), he stated that "the positive process steps in [the two claims] are identical," that "[t]he only difference is in the preamble, *i.e.*, the intended uses of the two processes," and that "the actual process steps of the two sets of claims are the same." ECF No. 149-5 at 2. The "identical" "positive process steps" were the "produced" and "transformed" limitations—the step of "administering" *differed* between the claims since each application's claims recited *different* medical uses. Moreover, the Examiner made it clear that he was referring to multiple "steps." *Id.*; *see also* Defs.' Opening Br., ECF No. 119-1 at 14-15. The statements that Biogen now seeks to disavow simply confirmed the Examiner's view, and the fact that this position was repeated reinforces that it was not a lone "mistake" for which Biogen can now seek a mulligan. In any event, even if the statements were, as Biogen asserts, a "mistake" and "in error," the Federal Circuit has rejected arguments to ignore prosecution statements like this as "inimical to the public notice function provided by the prosecution history." *Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc.*, 222 F.3d 951, 957 (Fed. Cir. 2000) (describing patentee's argument as a "request for a mulligan" and explaining that the public is "entitled to rely" on the file history). The portions of the file history discussed above underscore the correct construction of this claim, just as the file history did in *Monsanto*. 503 F.3d at 1358.

* * *

In short, *Monsanto* is fatal to Biogen's case. The Federal Circuit considered a claim having exactly the same architecture as Biogen's—a process with a step requiring the use of a particular product, which in turn was made according to additional process limitations. It

squarely held that all of the process limitations, including the process limitations nested within the product-by-process limitation, were steps that had to be carried out during the term of the patent. *Monsanto*, 503 F.3d at 1358.

II. BIOGEN’S ADDITIONAL ARGUMENTS ARE MERITLESS.

The Federal Circuit’s decision in *Monsanto* controls the outcome here and should end the matter. Biogen, however, makes two additional arguments as to why the “produced” and “transformed” limitations need not be carried out during the term of the patent. These arguments are also without merit.

A. The *Monsanto* Rule Does Not Lead to Absurd Results.

Biogen argues that following the decision in *Monsanto* by treating the “produced” and “transformed” limitations like any other process limitations would lead to absurd results. The bogeyman that Biogen conjures is that under Defendants’ construction, its claim would be worthless because it would never be infringed. *E.g.*, Tr. 84:10-85:7. Even if this were accurate (it is not), this line of reasoning would be irrelevant. Absurd or not, courts must follow binding precedent such as *Monsanto* here. *See State Oil Co. v. Khan*, 522 U.S. 3, 20 (1997) (“[I]t is this Court’s prerogative alone to overrule one of its precedents.”). And in any event, the Federal Circuit has emphasized that its “settled practice” is to “construe the claim as written, not as the patentees wish they had written it.” *Chef Am., Inc. v. Lamb Weston, Inc.*, 358 F.3d 1371, 1373-74 (Fed. Cir. 2004) (adopting claim construction in a baking method that would require dough to be “burned to a crisp”). When the language of a claim points to a particular meaning, the Federal Circuit has routinely adopted that meaning even if that makes the claims practically useless. *Id.*

But here, there is nothing absurd, unfair or untoward about holding that there can be no infringement unless all of the steps of a method are performed during the term of the patent. It is the plain application of the undisputed, hornbook law to a process that, as Biogen admits, must

be carried out. Tr. at 168:19-169:2 (“the claims require the use of the DNA to produce the polypeptide”). The infringement statute itself expressly limits infringement to those who perform a patented process “during the term of the patent.” 35 U.S.C. § 271(a); *Monsanto*, 503 F.3d at 1359-60 (citing *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 774 (Fed. Cir. 1993)). Indeed, the Federal Circuit recently affirmed a summary judgment of non-infringement *in Biogen’s favor* on exactly this ground. *Sanofi-Aventis Deutschland GmbH v. Genentech, Inc.*, 473 Fed. App’x 885, 890-91 (Fed. Cir. 2012) (non-precedential).⁷

Biogen also claims that Defendants’ construction is absurd because it would require that the “administering,” “produced,” and “transformed” steps all be carried out by the same entity. Tr. at 61:15-62:8. That is incorrect. Biogen has asserted indirect infringement claims under 35 U.S.C. §§ 271(b) and (c) because Defendants make and distribute products for treating multiple sclerosis, but the claims require the actual administration of those products by doctors and patients. *See, e.g.*, Complaint, Case No. 10-CV-2760, ECF No. 1, ¶¶ 32-73. The Federal Circuit sitting *en banc* recently emphasized that in such circumstances, where a party is accused of inducing or contributing to “acts that collectively practice the steps of the patented methods,” there is no need for a single party to have performed all of the steps of a claimed process.

Akamai Techs., Inc. v. Limelight Networks, 692 F.3d 1301, 1309 (Fed. Cir. 2012) (*en banc*).

Ultimately, Biogen’s argument that it would be aggrieved if the “produced” and “transformed” limitations must be performed during the term of the patent rings especially

⁷ Nor does Biogen’s inability to prove infringement of its claims by the current set of defendants mean that the claims are without value—these claims may prevent generic pharmaceutical companies from developing biosimilar versions of Biogen’s product (or, for that matter, a generic version of one of Defendants’ products). *See* 42 U.S.C. § 262(k)-(l); Nash & Workman, “A New Pathway for Follow-On Biologics,” 20 Fed. Cir. Bar J. 194 (2010). Biogen could assert that any such future generic drug maker infringes this patent because it would have performed all of the claimed process limitations during the patent’s term.

hollow given the significance of those limitations to the patent. There is no dispute that the step of administering interferon to a patient was not invented by Biogen—the patent’s specification states that naturally-occurring interferon had already been administered as an anti-viral treatment by various doctors around the world during the 1970’s. *See, e.g.*, ’755 patent, ECF No. 118-1 at 3:3-4:13 (discussing twelve diseases for which interferon had already been administered to patients). Here, Biogen’s argument that it invented *anything* is based on its contention that it made interferon by “produc[ing]” it using a “transformed” non-human host. As the specification recites, the alleged invention “allows the production of the[claimed] polypeptides in amounts and by methods hitherto not available,” *i.e.*, that the method of “administering” can now be done more easily because of advances in performing the “produced” and “transformed” steps. *Id.* at 6:57-59. While Biogen is right that the defendants will vigorously contest who *first* devised a method of making interferon-beta in non-human cells, there is nothing unfair or unjust in interpreting the patent in accordance with the ordinary rules governing process limitations. *See* Tr. at 62:9-23. That is not a technicality or a “get out of jail free card,” but rather a basic principle of patent law. Tr. at 84:19-24.

B. The Restriction Requirement Does Not Suggest a Contrary Result.

At the hearing, Biogen noted that a “restriction requirement” from early in prosecution required Biogen to divide its claims into five groups, including one for methods of treatment and another for methods of making polypeptides.⁸ *E.g.*, Tr. at 71:1-73:18. Biogen then asserted that this restriction requirement determined that its method of treatment claims were drawn to a separately patentable invention from claims to making the polypeptides. From these aspects of

⁸ A restriction requirement is a common procedure used by examiners, usually at the beginning of prosecution, in which the applicant is required to split applications with multiple types of claims into multiple applications for ease of examination.

the prosecution history, Biogen implies that this determination in 1982 somehow means that the steps of the polypeptide-making process cannot also be steps of the method of treatment claims that issued in 2009, and further suggests that this argument is irrefutable because restriction requirements cannot be reviewed in court. Tr. at 73:1-12.

Biogen is wrong for several reasons. First, a restriction requirement is not a determination on the merits that two claims are distinct. Rather, it is an administrative mechanism by which a patent examiner can divide the claims of one application into multiple applications, categorizing the claims into so-called “restriction groups” based on subject matter, in order to “ease the burden of examining that subject matter.” *Transco Prods. Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 558 (Fed. Cir. 1994); 35 U.S.C. § 121; see also 4A-12 Chisum on Patents § 12.01 (noting that a restriction requirement “prevent[s] subversion of the statutory fee structure . . . and preserve[s] the integrity of the system of examination and classification” of applications within the PTO). For example, while a claim to a new drug may require examination of related chemical compounds in the prior art, a claim to a method of treatment may also require examination of prior art regarding clinical uses of those compounds, in addition to the art regarding how that drug is made. See MPEP § 806.05(h).⁹ That does not mean the two inventions have no overlap—a method of using a drug plainly incorporates the drug, itself.

Second, the 1982 restriction requirement has nothing whatsoever to do with the claims that Biogen first submitted to the PTO in 1995 and which issued in 2009. The existence of a restriction requirement in 1982 does not change the basic fact—which Biogen concedes—that the claims it submitted years later were written to include “produced” and “transformed” claim

⁹ The “MPEP” or “Manual of Patent Examining Procedure” is published by the PTO on its website at <http://www.uspto.gov/web/offices/pac/mpep/>.

limitations that must be carried out to practice the claims. *E.g.*, Tr. 83:22-84:2. There is nothing in the restriction requirement that is inconsistent with that undisputed proposition: the method of treatment claims Biogen pursued in the application leading to the '755 patent include, as limitations of the claims, a process for preparing the polypeptide used in the treatment. At most, the restriction requirement could be viewed as inconsistent with construing this patent as directed *solely* to a method of preparing a polypeptide, as such claims would have belonged in a different restriction group. But that is not the construction that Defendants urge, as Defendants do not dispute that "administering," like "produced" and "transformed," is *also* a process step that must be carried out. Simply put, Defendants' argument has nothing to do with the distinctions between method-of-treatment and other types of claims used as a basis for the restriction requirement in 1982.

Biogen's statement that the restriction requirement operates as an unreviewable finding of the patentable distinction between methods of treatment and of making polypeptides is also incorrect, irrelevant, and misleading. Tr. at 73:6-18. The decision *to issue a restriction requirement* is not itself reviewable, but it in no way precludes the Court from later finding those claims unpatentable or invalid.¹⁰ Furthermore, an examiner's restriction requirement has no preclusive effect on infringement or validity arguments in litigation, including arguments that claims in separate groups are "not patentably distinct." *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 518 F.3d 1353, 1362-63 (Fed. Cir. 2008).

¹⁰ The statute mentioned during the hearing (35 U.S.C. § 121) only provides a "safe harbor" from certain "obviousness-type" double patenting attacks on validity that would use the claims to invalidate each other. Thus, a patentee who divides a single application into multiple patents in response to a restriction requirement cannot later be faulted for having procured multiple patents instead of just one. The restriction requirement has no impact on any other validity attacks besides those that fall within the strict bounds of the "safe harbor." *Pfizer*, 518 F.3d at 1362-63.

For all of these reasons, the restriction requirement is irrelevant to the claim construction questions before the Court.

III. CONCLUSION

Defendants' interpretation of the "produced" and "transformed" process limitations is required by settled Federal Circuit law in *Monsanto* and consistent with the long standing principle that process limitations must be performed during the term of the patent. Biogen's proposed interpretation is not only contrary to this settled law and to admissions Biogen made during prosecution, but Biogen is asking the Court to adopt an interpretation that it admits is unprecedented.

For the foregoing reasons, Defendants respectfully request that the Court construe "produced by a non-human host" and "transformed by a recombinant DNA molecule" as process limitations which should be treated like any other process step and thus, *inter alia*, must be performed during the term of the patent in order for there to be infringement.

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